Neurocrine Biosciences Reports Fourth Quarter and Year-End 2006 Results

February 1, 2007

SAN DIEGO, Feb. 1 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced its financial results for the fourth quarter and year ended December 31, 2006. For the three months ended December 31, 2006, the Company reported a net loss of $14.7 million or $0.39 loss per share compared to a net loss of $23.9 million or $0.65 loss per share for the same period last year. For the year ended December 31, 2006, the Company had a net loss of $107.2 million, or $2.84 loss per share compared with a net loss of $22.2 million, or $0.60 loss per share in 2005.

Revenues for the fourth quarter of 2006 were $9.4 million compared with $14.1 million for the same period last year. The decrease in revenues for the three months ended December 31, 2006 resulted primarily from license fee revenues arising from the Pfizer collaboration of $0.7 million and $4.4 million during the fourth quarter of 2006 and 2005, respectively. The sales force allowance earned under the collaboration agreement was $8.0 million for the fourth quarter of 2005. Additionally, the Company recognized milestones related to CRF drug candidate development earned under the GlaxoSmithKline (GSK) agreement of $8.0 million for the fourth quarter of 2006 compared to $1.0 million in fourth quarter of 2005.

Revenues for the year ended December 31, 2006, were $39.2 million, compared with $123.9 million for 2005. The decrease in revenues for the year ended December 31, 2006 resulted primarily from the achievement of $70.0 million in milestones from Pfizer during 2005. The Company recognized $6.6 million and $8.7 million in the form of sponsored development funding under the Pfizer collaboration agreement for the years ended December 31, 2006 and 2005, respectively. License fees recognized under the Pfizer collaboration were $6.5 million and $20.7 million for the years ended December 31, 2006 and 2005, respectively. The sales force allowance earned under the collaboration agreement was $16.5 million for 2006 and $22.0 million in 2005. The Company also recognized milestones under the GSK collaboration agreement of $9.0 and $2.0 million during the years ended December 31, 2006 and 2005, respectively.

Research and development expenses decreased by $6.2 million to $18.6 million for the fourth quarter of 2006 compared with $24.8 million for the same period in 2005, primarily resulting from decreased workforce, laboratory and external development costs. For the year ended December 31, 2006, research and development expenses were $97.7 million compared to $106.6 million last year. This $8.9 million decrease in year-to-date research and development expenses are primarily a result of the wind down of the Phase III indiplon clinical program.

Sales, general and administrative expenses were $7.1 million for the fourth quarter 2006 compared with $13.9 million for the same period in 2005, a direct result of our severance program during the third quarter of 2006. For the year ended December 31, 2006 sales, general and administrative expenditures totaled $54.9 million compared to $42.3 million in 2005. The increase in expenses from 2005 to 2006 resulted primarily from sales force costs.

The Company's balance sheet at December 31, 2006 reflected total assets of $389.7 million including cash, cash equivalents, and marketable securities of $182.6 million, compared with balances at December 31, 2005 of $483.1 million and $273.1 million, respectively.

Financial Guidance for 2007

The Company expects the net cash burn for 2007 to be approximately $80.0 million. The savings realized from the recent cancellation of the indiplon capsules trial will be utilized in pre-commercialization activities as well as Phase IIIb/IV trials during 2007. The Company expects to end 2007 with over $160 million in cash, cash equivalents, marketable securities and receivable equity in its property.

"As we begin 2007, we now plan to resubmit our New Drug Application (NDA) for indiplon capsules at the end of the 2nd Quarter of 2007. We reached this decision after reviewing data with independent statistical, regulatory and clinical consultants along with interactions with the FDA, and believe that indiplon will provide flexibility to treat insomnia as needed to help patients fall asleep quickly or return to sleep after a nighttime awakening. In parallel, our corporate objectives will be focused toward advancing the pipeline led by our GnRH and CRF programs. Neurocrine's R & D group continues to develop new therapeutic approaches as evidenced by our newest drug candidate, sNRI for neuropathic pain, which entered Phase I clinical trials in January of 2007," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

Indiplon

- Announced plans to resubmit NDA for indiplon capsules (5 mg and 10 mg) at the end of the 2nd quarter 2007.
- Substantially completed FDA requests for reanalysis of previously submitted indiplon capsules data.
- Plan to initiate market development and Phase IIIb/IV clinical trials in the second half of 2007.

R & D Pipeline Update

Neurocrine's clinical development group and corporate partners are advancing six drug candidates through clinical development and will report on R & D progress throughout 2007. Neurocrine scientists continue to build up Neurocrine's pipeline and meet the Company-wide goal of bringing one new compound into development each year.

GnRH Antagonists for endometriosis:

- Recently announced positive results from second Phase II 3-month dose-response clinical trial in endometriosis.
- Initiated a 6-month Phase IIb clinical trial with NBI-56418 for the treatment of endometriosis during the 4th Quarter 2006.

CRF1 Antagonists for IBS and Anxiety/Depression:

- GSK initiated Phase II "proof of concept" clinical trials in two indications, IBS and social anxiety disorder (SocAD) in late 2006.
- An additional lead compound is currently in Phase I multi-dose trials.

Urocortin 2 for CHF:

- Results from a Phase II dose response trial involving patients with stable congestive heart failure (CHF) demonstrated prominent hemodynamic activity with increased cardiac output during the 4-hour infusions. The infusions were generally safe and well tolerated and without untoward effects on renal, cardiac or hormonal assessments.
- Initiation of a Phase II trial with greater than 24-hour infusions of urocortin 2 are awaiting additional preclinical data to support the longer duration infusions.

Selective Norepinephrine Reuptake Inhibitor (sNRI) for Neuropathic Pain

- Neurocrine initiated Phase I clinical trials with its new clinical candidate for neuropathic pain in early 1st Quarter 2007.

GnRH Antagonists Report Positive Results and Expanded Phase II Development in Endometriosis

Neurocrine announced positive preliminary results from its second "proof of concept" safety and efficacy Phase II clinical trial over a 3-month treatment period using its proprietary, orally-active nonpeptide Gonadotropin- Releasing Hormone (GnRH) receptor antagonist (NBI-56418). The study was a multi-center, randomized, double-blind, placebo-controlled trial involving patients with a confirmed diagnosis of endometriosis evaluated in a parallel-group design in which 68 subjects were randomized to one of three treatment groups: placebo, 50 mg of NBI-56418, or 100 mg of NBI-56418 each administered twice daily. NBI-56418 demonstrated dose-related reductions of estradiol without evidence of increased risk of bone loss. The reductions in pain scores were reported within days of treatment initiation for some women and patients with initial improvement continued to benefit throughout the treatment period. The extent of estradiol suppression and lack of undesirable metabolic consequences suggest that even higher doses may be acceptable with the potential for greater symptom reduction. These results were consistent with positive results from the completion of the first 3-month "proof of concept" double-blind treatment period and additional 3-month follow up period of a parallel Phase II exploratory trial with NBI-56418 given once daily to endometriosis patients.

Neurocrine initiated a Phase IIb study in the 4th quarter of 2006 in which 240 patients with endometriosis will be treated over a 6-month treatment period. This multi-center, randomized, double-blind, study includes three treatment groups, with two doses of NBI-56418, 150 mg once a day and 75 mg twice daily, and an active comparator. In addition to confirming the effect of NBI-56418 on endometriosis symptoms, this study is designed primarily to assess the impact of longer treatment on bone mineral density as measured by DEXA scan at the conclusion of dosing and at 6-months and 12-months post- treatment. The 6-month results, together with data from the previous two Phase II studies will be the basis for securing agreement to a registration plan acceptable to the FDA.

CRF1 Antagonists for Anxiety/Depression and IBS in Proof of Concept Phase II Trials

The CRF collaboration between Neurocrine and GlaxoSmithKline (GSK) has identified multiple unique high affinity and selective antagonists for the CRF receptor that are currently in clinical development for anxiety-related disorders and irritable bowel syndrome (IBS). GSK recently initiated Phase II "proof of concept" clinical trials with a lead Corticotropin Releasing Factor R1 (CRF1) receptor antagonist compound for two indications, social anxiety disorder (SocAD) and IBS.

The first "proof of concept" trial is a Phase II double-blind, randomized, placebo controlled, multiple dose study to evaluate the safety and efficacy of the CRF1 antagonist compound in patients with SocAD. The four-arm study will include more than 200 adult subjects with Generalized Social Anxiety Disorder/Social Phobia. Efficacy, safety, tolerability and pharmacokinetics will be assessed. The clinical endpoints of the study include validated scales for assessment of anxiety disorders including the Liebowitz Social Anxiety Scale and the Social Avoidance and Distress Scale.

The second "proof of concept" trial is a Phase II double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of this compound in patients with IBS. Approximately 100 patients meeting established diagnostic criteria for IBS will be entered into this cross-over design trial. Standard assessments of safety, tolerability and pharmacokinetics will be conducted. The clinical endpoints reflect change in symptom frequency and severity via validated scales for IBS.

GSK has also advanced an additional lead CRF1 receptor antagonist into a Phase I single dose study in the 1st Quarter of 2006 and this compound is now in a Phase I multi-dose study.

Urocortin 2 for CHF Continues Preclinical Evaluation

Initial results of a Phase II study in patients with stable Congestive Heart Failure (CHF) indicate that urocortin 2 is generally well tolerated and that the predicted hemodynamic effects on systolic and diastolic blood pressure, heart rate, cardiac work and, most importantly, cardiac output occur over the entire 4-hour infusion. The study, a US Phase II study in stable CHF patients, was designed to assess various hemodynamic endpoints, safety and PK/PD over the 4-hour infusion treatment period. Cardiac output increased in the range of 6-54% among individual patients with a minimal increase in heart rate (5-10%). No abnormalities of renal function, electrocardiograms or biomarkers of cardiac injury (e.g. troponin-T) were observed.

Based on this data, it had been our intent to initiate additional Phase II studies in late 2006 with longer duration infusions of up to 72 hours. However, additional preclinical investigations are necessary to support longer exposures prior to proceeding. We believe that this data will be available in mid-2007.

sNRI for Neuropathic Pain Begins Clinical Development

Neurocrine has selected a new compound, a selective norepinephrine reuptake inhibitor (sNRI) for development for treatment of neuropathic pain and psychiatric disorders. Based on its selective pharmacologic effect as a norepinephrine reuptake inhibitor, this drug also has potential clinical utility in a variety of other therapeutic areas including psychiatry, gastroenterology and urology. Phase I clinical trials were initiated early in the 1st Quarter of 2007.

Additional Research Programs

Neurocrine's Research Group continues to advance novel small molecule compounds into clinical development. Neurocrine scientists are focusing on developing small molecule antagonists against G-protein coupled receptors.

Neurocrine is currently reviewing in preclinical studies a number of adenosine A2A receptor antagonists for the treatment of Parkinson's disease. The Company was awarded a grant from The Michael J. Fox Foundation (MJFF) to evaluate the neuroprotective effects of A2A antagonists in preclinical models of Parkinson's disease, specifically to assess their potential to modify early disease progression. This may also help to guide the preclinical selection of drug candidates in which both symptom relief and neuroprotective actions have been optimized.

Conference Call and Webcast Today at 5:00 PM Eastern Standard Time

Neurocrine will hold a live conference call and webcast today at 5:00 p.m. Eastern Standard Time (2:00 p.m. Pacific Standard Time). Participants can access the live conference call by dialing 1-800-896-8445 (US) or 785-830-1916 (International) using the conference ID# 7NBIX. The call can also be accessed via the webcast through the Company's website at http://www.neurocrine.com

If you are unable to attend the Webcast and would like further information on this announcement please contact the Investor Relations Department at Neurocrine Biosciences at (858) 617-7600. A replay of the Conference Call will be available approximately one hour after the conclusion of the call by dialing 1-800-839-3413 (US) or 402-220-7236 (International). The call will be archived for two weeks.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, irritable bowel syndrome, endometriosis and CNS related disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at http://www.neurocrine.com

In addition to historical facts, this press release may contain forward- looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's indiplon program and R & D pipeline. Specifically, the risks and uncertainties associated with the Company's indiplon program and planned commercialization activities, including but not limited to; risk that we will be unable to resubmit the indiplon capsule NDA in a timely manner or at all; risk that regulatory authorities may refuse to file our resubmission of the indiplon capsule NDA; risk that regulatory authorities may find our resubmission of the indiplon capsule NDA incomplete or insufficient or otherwise unapprovable or that approval may be delayed; risk that following approval of indiplon capsules, commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that we will not be able to independently commercialize indiplon capsules or find a marketing partner on reasonable terms or at all; risk that the indiplon capsule labeling granted by regulatory authorities may limit the commercial success of indiplon capsules; and risk relating to market acceptance of indiplon capsules following marketing approval. In addition, the Company faces risks and uncertainties with respect to the Company's R & D pipeline including risk that the Company's GnRH receptor antagonist, urocortin 2, CRF antagonist, and sNRI clinical candidates will not proceed to later stage clinical trials and that the Company's adenosine A2A receptor antagonist preclinical candidates will not advance to clinical trials; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; risk that the Company will be unable to raise additional funding required to complete development of all of its product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2005 and the Company's report on Form 10-Q for the quarter ended September 30, 2006. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(in thousands except for loss per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2006 (unaudited)	2005	2006 (unaudited)	2005
Revenues:				
Sponsored research and development	$213	$753	$6,716	$9,187
License fees and milestones	9,227	5,358	16,038	92,702
Sales force allowance	--	8,000	16,480	22,000
Total revenues	9,440	14,111	39,234	123,889
Operating expenses:				
Research and development	18,608	24,765	97,678	106,628
Sales, general and administrative	7,095	13,940	54,873	42,333
Total operating expenses	25,703	38,705	152,551	148,961
Loss from operations	(16,263)	(24,594)	(113,317)	(25,072)
Other income and (expenses):				

Interest income, net	1,543	626	6,576	2,858
Other income (expense), net	8	60	(464)	23
Total other income	1,551	686	6,112	2,881
Net loss	$(14,712)	$(23,908)	$(107,205)	$(22,191)
Net loss per common share:				
Basic and diluted	$(0.39)	$(0.65)	$(2.84)	$(0.60)
Shares used in the calculation of net loss per common share:				
Basic and diluted	37,894	36,992	37,722	36,763

NEUROCRINE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2006 (unaudited)	December 31, 2005
Cash, cash equivalents and marketable securities	$182,604	$ 273,068
Other current assets	11,054	6,242
Total current assets	193,658	279,310
Property and equipment, net	91,378	99,307
Prepaid royalty	94,000	94,000
Other non-current assets	10,641	10,506
Total assets	$389,677	$ 483,123
Current liabilities	$20,116	$33,693
Long-term liabilities	54,845	59,326
Stockholders' equity	314,716	390,104
Total liabilities and stockholders' equity	$389,677	$483,123

SOURCE Neurocrine Biosciences, Inc.
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